final delivery or sale of the device to the ultimate consumer or user.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 59159, Nov. 27, 2001]

Subpart B—Procedures for Device Establishments

§ 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term ''device'' includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the person initiating specifications, is not required to list those devices.

(3) Repackages or relabels a device;

(4) Acts as an initial importer; or

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) No registration or listing fee is required. Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the act.

(c) Registration and listing requirements shall not pertain to any person who:

(1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;

(2) Sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices.

(3) Acts as a wholesale distributor, as defined in § 807.3(s), and who does not manufacture, repackage, process, or relabel a device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 5466, Jan. 19, 2001; 66 FR 59160, Nov. 27, 2001]

EFFECTIVE DATE NOTE: At 66 FR 5466, Jan. 19, 2001, § 807.20 was amended by adding paragraph (d), effective Jan. 21, 2003. For the convenience of the user, the added text is set forth as follows:

§ 807.20 Who must register and submit a device list?

* * * * *

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with

the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of §807.31 remain applicable.

§ 807.21 Times for establishment registration and device listing.

(a) An owner or operator of an establishment who has not previously entered into an operation defined in §807.20 shall register within 30 days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within 30 days after receiving registration forms from FDA. FDA will mail form FDA-2891a to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows:

First letter of owner or operator name	Date FDA will mail forms
A, B, C, D, E	March.
F, G, H, I, J, K, L, M	June.
N, O, P, Q, R	August.
S, T, U, V, W, X, Y, Z	November.

(b) Owners or operators of all registered establishments shall update their device listing information every June and December or, at their discretion, at the time the change occurs.

[58 FR 46522, Sept. 1, 1993]

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on Form FDA–2891 (Initial Registration of Device Establishment). Forms are available upon request from the Office of Compliance, Center for Devices and Radiological Health (HFZ–307), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDD–2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under §807.35(a). The forms will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in §807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

(b) The initial listing of devices and subsequent June and December updatings shall be on form FD–2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate form FD–2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device: *Provided*, The variation does not change the function or intended use of the device. In lieu of form FD–2892, tapes for computer input or hard copy computer output may by submitted if equivalent in all elements of information as specified in form FD–2892. All formats proposed for use in lieu of form FD–2892 require initial review and approval by the Food and Drug Administration.

(c) The listing obligations of the initial importer are satisfied as follows:

(1) The initial importer is not required to submit a form FDA-2892 for those devices for which such initial importer did not initiate or develop the specifications for the device or repackage or relabel the device. However, the initial importer shall submit, for each device, the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importers; and

(2) The initial importer shall update the information required by paragraphs (c)(1) of this section at the intervals specified in §807.30.

[43 FR 37997, Aug. 25, 1978, as amended at 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998]